

**Área: FIS**

## Study of the Degradation Kinetics of Prednisolone in a Compounded Gel-Cream for the Treatment of Folliculitis

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### Highlights

Prednisolone 1% gel-cream showed zero-order kinetics ( $R^2=0.9511$ ,  $k=2.96 \times 10^{-3}$  mg/mL·day),  $t_{1/2} \approx 37.7$  days, and 15% loss after 30 days, suggesting initial concentration adjustment for  $\pm 10\%$  variation.

### Resumo/Abstract

The stability study of a compounded gel-cream containing 1% prednisolone was carried out using High-Performance Liquid Chromatography (HPLC) over a 60-day storage period at 45 °C, with samples collected every 15 days. The concentrations obtained were fitted to the kinetic models of zero-order ( $C \times t$ ), first-order ( $\ln C \times t$ ), and second-order ( $1/C \times t$ ) to determine the degradation behavior of the drug.

The determination coefficients ( $R^2$ ) obtained for the kinetic models were 0.9511 for zero-order, 0.9365 for first-order, and 0.7840 for second-order, indicating that the zero-order model provided the best fit to the experimental data. Comparison of the determination coefficients revealed that the zero-order model provided the best fit ( $R^2 = 0.9511$ ), demonstrating that the degradation of prednisolone occurs at a constant rate, independent of the remaining drug concentration. In other words, the system degrades a fixed amount of prednisolone per unit of time — a behavior commonly observed in semisolid pharmaceutical systems and suspensions, where the active ingredient is dispersed rather than fully dissolved.

The regression analysis resulted in the equation  $C=0,2061-0,00296t$ , where  $C$  denotes the concentration ( $\text{mg}\cdot\text{mL}^{-1}$ ) and  $t$  the time (days). From this equation, the degradation rate constant ( $k$ ) was determined to be  $2.96 \times 10^{-3}$   $\text{mg}\cdot\text{mL}^{-1}\cdot\text{day}^{-1}$ , and the half-life ( $t_{1/2}$ ) was estimated at approximately 37.7 days. The concentration decreased from 0.2230 to 0.0327 mg/mL over 60 days, confirming significant degradation under accelerated conditions. After 30 days, a 15% loss in prednisolone content was observed, suggesting that a slightly higher initial concentration could ensure stability within  $\pm 10\%$  variation, maintaining therapeutic efficacy even at 45 °C.

It is concluded that the degradation of prednisolone in the gel-cream follows zero-order kinetics, characterized by a constant rate of active ingredient loss, reinforcing the importance of storing the product under controlled temperature and light conditions to ensure therapeutic efficacy and compliance with pharmaceutical stability guidelines.

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